IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MERIX PHARMACEUTICAL CORPORATION, Plaintiff, vs. GLAXOSMITHKLINE CONSUMER HEALTHCARE, L.P. and SMITHKLINE BEECHAM CORPORATION, Defendants.	)	No. 05 C 1403 Magistrate Judge Schenkier

MEMORANDUM OPINION AND ORDER

Presently pending before the Court is plaintiff's motion to compel production of documents relating to plaintiff's "Valtrex claims" (doc. # 107). For the reasons set forth below, plaintiff's motion is granted.

I.

In March 2005, plaintiff Merix Pharmaceutical Company filed this action challenging the advertising by defendants Glaxosmithkline Consumer Healthcare, L.P. and Smithkline Beecham Corporation (collectively, "defendants" or "GSK") of two of the defendants' products: "Abreva," an over-the-counter cold sore drug, and "Valtrex," a prescription medication used to treat cold sores, genital herpes and shingles. The original complaint (and now, the second amended complaint) asserts that the advertising is false and misleading, and on that basis, pleads a federal claim under the Lanham Act, 15 U.S.C. § 1125(a), and supplemental state law claims under the Illinois Consumer Fraud and Deceptive Business Practices Act ("the Consumer Fraud Act"), 815 ILCS 505/2, the Illinois Uniform Deceptive Trade Practices Act ("the Deceptive Trade Practices Act"),

815 ILCS 510/2, and the Illinois common law of unfair competition. As it pertains specifically to the Valtrex claim, the complaint alleges that defendants' marketing statements that Valtrex is a "One-day Cold-Sore Treatment" for cold sores and a 3-Day Outbreak Therapy" for general herpes are false and misleading.

On July 15, 2005, defendants filed a motion for judgment on the pleadings as to the Valtrex claims, pursuant to Federal Rule of Civil Procedure 12(c). Defendants argued that all of plaintiff's legal theories failed because a document attached to the complaint, the FDA-Approved Prescribing Information, shows that defendants' advertising statements about Valtrex do nothing more than repeat what the FDA requires defendants to disclose to patients and doctors.

During the pendency of that motion for judgment on the pleadings, a discovery dispute arose between the parties concerning a particular request for production of documents served by plaintiff. In that request, plaintiff sought (as relevant here) "[any] and all documents which refer or relate to any communications with the FDA or FTC concerning" Abreva and Valtrex. That discovery dispute resulted in defendants moving for a protective order with respect to that particular document request. After full briefing and argument, in an order dated November 16, 2005, this Court granted that motion in part (doc. # 77). With respect to documents pertaining to Abreva, the Court ordered production communications between defendants and the FDA and/or FTC regarding the efficacy and/or speed of Abreva, Docosonal (a related drug) and/or Releev (plaintiff's competing product) in treating cold sores, and any comparisons between Abreva and/or Docosonal on the one hand, and prescription medications on the other hand as to their efficacy and/or speed in treating cold sores. In that same order, this Court held that "[t]his ruling shall apply to Valtrex and Valocyclovir [a

related drug], in the event that the presiding district judge denies the motion for judgment on the pleadings as to the Valtrex claims."

In a Memorandum Opinion and Order dated June 28, 2006 (doc. # 95), the presiding district judge did just that: he denied defendants' motion for judgment on the pleadings. In that opinion, the court held that plaintiff's allegations of fraud were sufficiently detailed to meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). The court then rejected defendants' argument that plaintiff's claims under the Consumer Fraud Act and Deceptive Trade Practices Act were barred by the statutory exemptions providing that those acts do not apply to "[a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of . . . the United States" (in the case of the Consumer Fraud Act, 815 ILCS 505/10(b)(1)), or to "conduct in compliance with the orders or rules or a statute administered by a federal, state or local governmental agency" (in the case of the Deceptive Trade Practices Act, 815 ILCS 510/4(1)). In so holding, the court found that on the motion for judgment on the pleadings, there was insufficient information to determine whether the Valtrex advertising claim fell within those statutory exemptions (Mem. Op. at 5-6). The court also denied the motion to dismiss as to the Lanham Act and common law claims, noting that the fact that "allegedly false statements are within the purview of the FDA" did not warrant dismissal (*Id.* at 6).

Shortly thereafter, on August 2, 2006, defendants filed a motion for partial summary judgment with respect to the Valtrex claims (doc. # 100). In that motion, defendants sought to supplement the factual record the court had found insufficient by offering certain of defendants' Valtrex advertisements, for the purpose of demonstrating that the language in the advertisements falls within the FDA-Approved Prescribing Information. During a proceeding in this case on

August 22, 2006, plaintiff indicated its desire for discovery on the Valtrex claims for which defendants seek summary judgment; defendants indicated their contrary desire to continue to forego discovery on the Valtrex claims, pending ruling on the motion for partial summary judgment. This Court directed the parties to meet and confer for the purpose of determining what discovery plaintiff fairly would need to respond to the motion for summary judgment.[1]

The meet and confer process resulted in defendants agreeing to produce three categories of documents sought by plaintiff: Valtrex advertising and marketing materials that make the One-Day Cold-Sore Treatment and 3-Day Outbreak Therapy claims at issue in defendants' motion for partial summary judgment; Valtrex brand positioning documents that refer or relate to the Valtrex One-Day Cold-Sore Treatment and 3-Day Outbreak Therapy claims at issue in the summary judgment motion; and communications between the FDA and defendants and/or their attorneys referring or relating to the advertising and marketing of Valtrex with respect to the One-Day Cold-Sore Treatment and 3-Day Outbreak Therapy claims at issue. The parties have been unable to agree on two additional requests made by plaintiff, which are now the subject of plaintiff's motion to compel: (1) the Valtrex New Drug Application ("NDA"), subject to the same limitations set forth in the Court's November 16, 2005 order concerning production of NDA documents concerning Abreva ("the NDA materials"); and (2) documents generated by defendants, or anyone on their behalf, that refer or relate to any substantiation, or lack thereof, of the Valtrex One-Day Cold-Sore Treatment and 3-Day Outbreak Therapy claims ("the substantiation materials") (Pl.'s Motion, Ex. F, at 1-2 (Requests Nos. 1, 3)).

[1]The Court contemplated that this procedure would proceed in lieu of plaintiff filing with the presiding district judge a formal motion pursuant to Federal Rule of Procedure 56(f). And, in light of the pending discovery motion before this Court, the presiding district judge has deferred briefing on the summary judgment motion indefinitely (doc. #117).

In opposing the motion to compel, defendants raise a number of arguments which may be grouped into three overarching categories: (1) that the requested discovery is irrelevant to the claims raised on the summary judgment motion; (2) that there are independent legal bars to plaintiff obtaining the information it seeks; and (3) that even if neither of those two arguments were sufficient to bar production, the Court should deny the motion to compel because the scope of the production would impose an undue burden on defendants. We address each of these arguments in turn.

II.

Federal Rule of Civil Procedure 26(b)(1) authorizes discovery of "any matter," not privileged, that is relevant to the claim or defense of any party." The rule provides that "[r]elevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." It is well settled that "relevance" for purposes of admitting evidence at trial, and for good reason: "[s]ince decisions as to relevance . . . are made for discovery purposes well in advance of trial, a flexible treatment of relevance is required . . ." Advisory Committee Notes to 1970 Amendment; *see also Murata Mfg. Co., Ltd. v. Bel Fuse Inc.*, 422 F.Supp.2d 934, 945 (N.D. Ill. 2006); *Pizel v. Monaco Coach Corp.*, 224 F.R.D. 642, 643 (N.D. Ind. 2004). While the 2000 amendments to Rule 26(b)(1) narrow the scope of information presumptively discoverable from that which is relevant to the subject matter of the case to that which is relevant to a claim or defense, the 2000 amendments did not alter the rule that relevance for discovery purposes is more generous than it is for determining admissibility of evidence at trial.

Plaintiff's theory of relevance for the requested information is straight forward. Plaintiff says that the FDA-Approved Prescribing Information refers to one-day and three-day recommended *dosages*, and do not support defendants' advertising materials marketing Valtrex as one-day and

three-day *treatments*, but also to determine whether they are otherwise substantiated or not. Plaintiff's position is that the words "treatment" or "therapy" falsely represents (or implies) the efficacy of the dosages, and that plaintiff is therefore entitled to request it to test the basis for that representation of efficacy. We agree that documents concerning the efficacy of the one-day or three-day treatment are relevant to plaintiff's theory, and are documents that plaintiff should have in order to respond to defendants' summary judgment motion. We also agree that it is reasonable for plaintiff to believe the documents that would substantiate (or contradict) the efficacy of a one-day or three-day dosage would be found in the NDA file.

Defendants' argument that this information is irrelevant rests, at bottom, on the proposition that the wording of the advertisements hews so closely to that set forth in the FDA-Approved Prescribing Information that nothing else matters (Defs.' Resp. at 8-9). To rule on that basis would require us to accept defendants' summary judgment argument that the claims in the Valtrex advertisements "are Specifically Authorized by the FDA" (Defs.' Partial SJ Mem., doc. # 101, at 9). However, that argument has not yet been tested by briefing, and has not yet been ruled on by the presiding district judge before whom it is pending. In our view, it is appropriate to permit the plaintiff to obtain the discovery that will allow it to argue not only why the advertisements do not meet the language in the FDA-Approved Prescribing Information, but also to determine whether they are otherwise substantiated or not.

Thus, for the foregoing reasons, we conclude that the discovery at issue meets the definition of relevance set forth in Federal Rule of Civil Procedure 26(b)(1).

III.

Defendants argue that this discovery nonetheless should be foreclosed for various other legal reasons. We have considered those arguments, and find them unpersuasive.

First, defendants argue that this requested discovery is an effort to "second guess" the FDA's decision to approve Valtrex (Defs.' Resp. at 8-9). Defendants made the same argument in seeking to prevent production of the NDA materials concerning Abreva. The Court finds this recycled argument no more persuasive now then it did with respect to the Abreva claim. Plaintiff's theory is not that the FDA was incorrect in approving Valtrex for use, but rather that the scope of the FDA approval does not support the advertising claims that defendants made for Valtrex.

Second, defendants argue that the requested discovery is not supported by plaintiff's claims under the Lanham Act because their advertisements "closely track" the information in the FDA-Approved Prescribing Information, and thus cannot be challenged under the Lanham Act because the advertising claims are "truthful and clear on their face" (Defs.' Resp. at 11-12). Once again, this argument would require us to accept defendants' summary judgment theory before it has been fully briefed and ruled upon, which we decline to do in deciding this discovery motion.

Third, for similar reasons, the Court finds unpersuasive defendants' argument that plaintiff lacks standing to assert claims under the Lanham Act, the Consumer Fraud Act, or the Deceptive Practices Act with respect to any genital herpes claims because plaintiff does not market a genital herpes medicine (Defs.' Resp. at 13-14). Again, we are unwilling to deprive plaintiff of discovery to respond to a summary judgment motion merely on defendants' representation that its summary judgment motion is meritorious and thus will render any discovery unnecessary. We further note that, even if this particular argument had merit, it would not have a basis to prevent discovery with

respect to the "One-Day Cold-Sore Treatment" claim, which is not the subject of defendants' challenge to plaintiff's standing.

IV.

Finally, we address the issue of undue burden. We do so separately with respect first to the NDA materials, and then to the substantiation materials.

A.

At the outset, we note that the parties spar about whether the Court's November 16, 2005 order already has ruled that the Valtrex documents and the NDA file must be produced (to the extent that they deal with the efficacy and/or speed of the product). Plaintiff says that the order clearly requires defendants to do so (Pl.'s Reply Mem. at 9); defendants say that this Court's earlier order does not require that production (Defs.' Response at 11 n. 5). The plain language of this Court's November 16, 2005 order supports the plaintiff's position. In that order, the Court required production of NDA documents concerning the efficacy and speed of Abreva, and stated that the ruling "shall apply to Valtrex and Valacyclovir, in the event that the presiding district judge denies the motion for judgment on the pleadings as to the Valtrex claims" (doc. # 77). The motion for judgment on the pleadings has been denied.

Defendants' argument that the order did not apply to Valtrex flies in the face of the plain language of the order. Moreover, defendants' argument that the document request that gave rise to the November 16, 2005 order dealt only with an "Abreva document request" (Defs.' Resp. at 11 n. 5) is contrary to the language of defendants' motion for protective order as to that earlier request. In that motion, defendants stated that plaintiff's request sought the production of documents which "refer or relate to any communications with the FDA or FTC concerning Abreva, Zovirax, *Valtrex*,

Denavir, Docosanol, *Valacyclovir*, Pencicyolvir, and Releev. (Merix's Doc. Req. No. 11.)" (Defs.' Mem. In Support of Motion for Protective Order, Doc. # 65, at 1) (emphasis added). While defendants are correct that the November 16, 2005 order specifically referred only to documents concerning the speed and/or efficacy of treatment of cold sores (which was the particular issue raised concerning Abreva), that order contemplated that efficacy documents on the Valtrex claim (whether they relate to cold sores or genital herpes) would be produced if the motion for judgment on the pleadings was denied.

Thus, what defendants in substance ask is that the Court reconsider its earlier ruling that documents in the NDA file concerning the efficacy of Valtrex would be produced if the motion for judgment on the pleadings was denied. Defendants argue that production of the NDA application file concerning Valtrex would be unduly burdensome because of the sheer size of that file: approximately 80 boxes consisting of 175,000 pages. Defendants claim that it would take "*months* to organize these materials, remove safety and private patient information, review and make confidentiality designations, and ultimately produce the Valtrex NDA" (Defs.' Mem. at 13) (emphasis in original). For this reason, defendants argue that the Court should exercise our authority to bar the discovery because the burden of producing the NDA documents will substantially outweigh their probative value.

Even accepting defendants' statement concerning the volume of the Valtrex NDA materials, which is unsupported by a declaration from a person familiar with those files, we believe that defendants have overstated the magnitude of the task that production would require. To begin with, all of the Valtrex NDA documents are located in identified boxes; therefore, complying with the production requests would not require defendants to search remote nooks and crannies of their

organization in order to locate responsive materials. Moreover, the search for materials in the NDA Valtrex file will be focused: only documents concerning the speed and efficacy of Valtrex must be located and produced. We expect that sophisticated companies such as the defendants will maintain a new drug application file in an intelligent, organized fashion, and that knowledgeable people in the organizations who are familiar with those files would be able to locate the materials in far less time than defendants claim. To the extent that the task of locating responsive documents is made more difficult because of the manner in which the file is maintained or the persons who are selected to perform the search, that is a burden of defendants' own making that does not justify insulating the materials from production. *Residential Constructors, LLC v. ACE Property and Cos.*, No. 2:05-CV-1318-BES-GWF, 2006 WL 1582122 (D. Nev., June 5, 2006) (citing *Caruso v. Coleman Corp.*, 157 F.R.D. 344, 349 (E.D. Pa. 1994).

B.

Defendants' undue burden argument with respect to the substantiation documents (to the extent that they are not already in the Valtrex NDA file) is more obscure. Defendants do not disclose whether any such documents exist, and if so, what difficulty they would encounter in locating and producing them. Indeed, while the defendants' memorandum implies that such documents exist (Defs.' Resp. at 2), in the correspondence preceding the current motion defendants suggested that no such documents exist (Pl.'s Reply Mem., Ex. B, at 2). If defendants indeed have no substantiation documents (again, apart from what may be continued in the NDA Valtrex file), then it imposes no burden on them to simply say so. If, on the other hand, defendants have substantiation documents, they have failed to demonstrate that any burden – much less an undue burden – would be imposed by requiring their production.

V.

Plaintiff seeks an award of attorneys' fees and costs incurred in filing the motion to compel. Rule 37 of the Federal Rules of Civil Procedure states that if a motion to compel is granted, the Court "shall, . . . require the party . . . whose conduct necessitated the motion . . . to pay to the moving party the reasonable expenses incurred in making the motion, including attorney's fees, unless the court finds that the motion was filed without the movant's first making a good faith effort to obtain the disclosure or discovery without court action, or that the opposing party's nondisclosure, response, or objection was substantially justified, or that other circumstances make an award of expenses unjust." Fed. R. Civ. P. 37(a)(4). Defendants argue that fees and costs should not be awarded, because their position was substantially justified (Defs.' Resp. at 14-15).

We disagree. We recognize a party's position in resisting discovery may fail, and yet still be substantially justified. But here, that is not the case. For the reasons we have set forth in this opinion, we do not believe there is a genuine dispute that the requested documents meet the standard of relevance under Rule 26(b)(1); nor do we believe that there are other legal impediments that would otherwise bar their production. Moreover, for the reasons described above, defendants' undue burden argument as to the NDA documents is meritless, as we believe defendants should have recognized in light of the Court's November 16, 2005 ruling. Indeed, defendants' argument that the November 16, 2005 order has no relevance here disregarded the wording of that order, and the discovery request that lead to that order.

In these circumstances, we find an award of attorneys' fees and costs appropriate under Rule 37(a)(4). Accordingly, we grant plaintiff's request for an award of attorneys' fees and costs, limited

to the reasonable attorney time spent and expenses incurred in preparing the motion to compel and the reply memorandum in support of that motion.

CONCLUSION

For the foregoing reasons, plaintiff's motion to compel production of documents relating to the Valtrex claims (doc. # 107), including its request for attorneys' fees and costs under Federal Rule of Civil Procedure 37(a)(4) is GRANTED.

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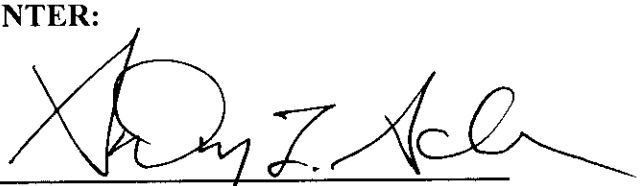

SIDNEY I. SCHENKIER
United States Magistrate Judge

Dated: October 11, 2006